



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/540,123

06/22/2006

Hermann Gohl

07552.0056

1075

22852

7590

07/16/2010

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

STEELE, JENNIFER A

ART UNIT

PAPER NUMBER

1782

MAIL DATE

DELIVERY MODE

07/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,123	Applicant(s) GOHL ET AL.	
	Examiner JENNIFER STEELE	Art Unit 1782	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-21 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) 8-19,26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7, 20-21 and 24-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/20/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

Declaration Under 37 CFR § 1.132

The Declaration under 37 CFR 1.132 filed 4/20/2010 is sufficient to overcome the rejection of claim 1, 3-7, 20-21 and 24-25 based upon the evidence presented that the pore density of Kawata is not in the claimed range of 10,000 to 150,000 pores per mm². The Declaration states that Fig. 1 of Kawata can be used to calculate the pore density of Iwata which is actually 2,600,000 per mm². The Declaration also states that the scale of Figure 1 can be confirmed by measuring the pore diameter which is in the claimed range of 0.05 to 1 micron. The evidence is sufficient to show that Kawata does not present an embodiment in the claimed range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1782

1. Claim 1, 3, 5-7, 20-21, 24-25 rejected under 35 U.S.C. 103(a) as unpatentable over Buck (US 4,935,141) in view of Gorsuch et al (US 6,802,971) and Wang et al (US 6,045,899). Claim 1 describes a permselective asymmetric hollow fiber membrane suitable for hemodialysis comprising:

- at least one hydrophobic polymer and
- at least one hydrophilic polymer
- wherein said hollow fiber membrane has a four layer structure comprising
 - a first inner separation layer in the form of a dense rather thin layer
 - a second layer in the form of a sponge structure
 - a third layer in the form of a finger structure
 - and a fourth outer layer in the form of a sponge layer having an outer surface having pores with sizes in the range of 0.5-3 micron, the number of said pores on the outer surface of the sponge layer being in the range of 10,000 to 150,000 pores per mm²

Buck teaches a permeable asymmetric membrane preferably in the shape of hollow fibers (ABST). Buck teaches a three layer membrane with a dense inner layer of thickness of less than 1 micron, a second sponge layer with a thickness of 5 micron and a third open finger like structure having a thickness of 20 to 60 micron. Buck teaches a selectively permeable asymmetric membrane in which the membrane includes a

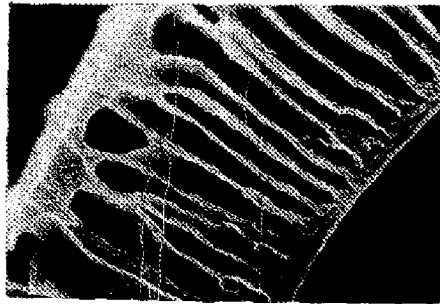
- A first layer comprising a dense, thin skin layer including substantially uniform pore openings (col. 2, lines 5-18). The first layer has a pore size

of about 80 angstroms (0.008 micron). The pores then increase to the outer side (col. 4, lines 37-49).

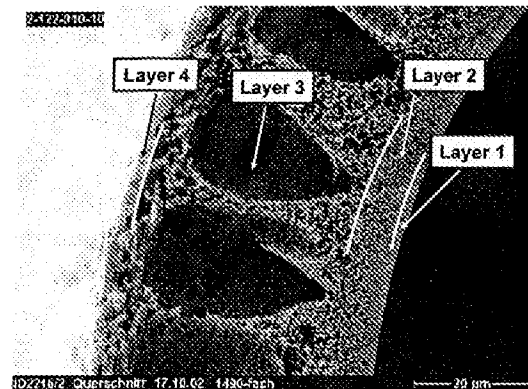
- A second intermediate layer in contact with the first layer in the form of a sponge which has a diffusive permeability which is higher than that of the first layer (col. 2, lines 5-18). .
- And a third intermediate second layer and including a finger-like structure providing mechanical stability for the membrane. The third layer includes the finger-like structure and is equated with Applicants third finger structure layer (col. 2, lines 5-18).

Buck shows the structure in Fig. 1b. Further, a side-by-side comparison of the photomicrographs of Buck '141 and the current application indicates that the prior art to Buck has the same structure as the current application.

Buck differs from the current application and does not explicitly teach a fourth and outer layer. Buck appears to inherently have an outer layer, different from the finger-like structure. As shown in the figures below, with prior art of Buck '141 on the left and the current application on the right.



Buck (US 4,935,141) FIG. 1b



Current Application
10/540,123

Fig. 4

Buck differs and does not teach the pore size of the outer layer.

Buck differs and does not teach the number of pores on the outer surface or pore density.

As to Applicant's claimed four layers, Gorsuch teaches an ultrafiltration membrane comprising a plurality of elongated hollow fibers each fiber having an interior lumen extending along the fibers length and the fiber will have a plurality of zones between the inner and outer surfaces of the fiber (ABST). Gorsuch teaches the fiber has 4 zones as shown in Fig. 1. The zones are equated with layers. The zones are configured where each zone is characterized by a different mass pore density based on the average nominal pore size in the respective zones. Gorsuch teaches zone 1 on the outer surface has the principal effect in the filtration process for controlling the trans-membrane flux which is dependent on pore size, porosity and virtual membrane thickness (col. 3, lines 5-16). Gorsuch teaches the pores sizes of zone 1, the surface layer, is 0.7 and in the claimed range (col. 5, line 24). Gorsuch teaches that the largest leverage to obtaining optimum trans-membrane flux is the radius of the pores and the

Art Unit: 1782

next largest lever is the porosity or number of pores/unit area (col. 4, lines 27-33).

Gorsuch presents a finding that one of ordinary skill in the art could employ a surface layer zone with the claimed pore size and optimizing the pore density motivated to control the filtration or flux through the membrane.

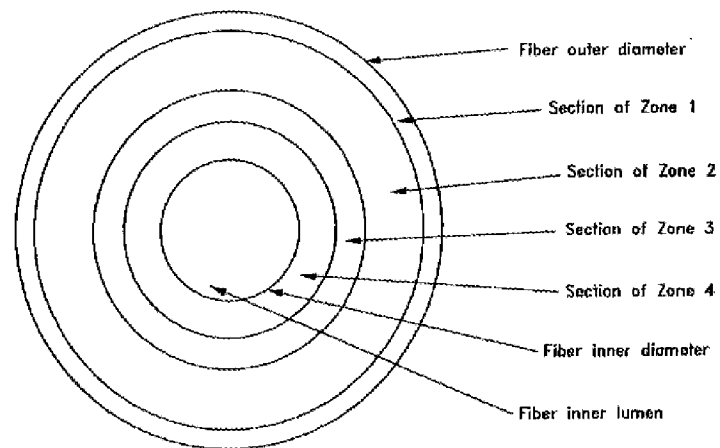


FIG. 1

As Gorsuch does not teach a pore density in the claimed range, Wang is relied upon for teaching it is known in the art to employ the claimed pores per unit area. Wang teaches a membrane for microfiltration where the membrane has a skin layer and a support layer. The skin layer has pores with an average diameter of 0.1 to 10 microns in the claimed range and the secondary porous support is an asymmetric region of gradually increasing pore sizes to an average diameter of from 5 to about 100 times the diameter of the skin pores (col. 6, lines 22-34). Wang teaches the density of the skin pores is at least 8 pores per 1000 micron² and more than 50 pores per 1000 micron² (col. 13, lines 13-34). This is 8,000 to 50,000 pores per mm² and in the claimed range.

Art Unit: 1782

Wang presents a finding that one of ordinary skill in the art could produce a membrane with the claimed pore density and surface pore size.

Buck differs from the current application and does not teach a four layer hollow fiber membrane where the surface layer has the claimed pores size and pore density. Gorsuch presents a finding that one of ordinary skill in the art could have employed a fourth outer layer where the outer layer has a pore size in the claimed range and the number of pores per unit area is a key variable in optimizing the flux through the membrane. Wang presents a finding that it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the claimed pore size and density of the surface layer and the results of the combination would have been predictable in producing a hollow fiber membrane with improved the flow rate and flux rate. It would have been obvious to one of ordinary skill in the art to combine the features of Buck, Gorsuch and Wang motivated to achieve the desired filtration flow and flux through the hollow fiber membrane.

As to claim 3, Buck teaches a diffusive permeability of 110 to 150×10^{-5} cm/sec (col. 4, lines 65-66) which is equivalent to 11 to 15×10^{-4} cm/sec and overlaps the claimed range of 15 to 17×10^{-4} cm/sec. Buck teaches that this diffusive permeability is for substances which are to be removed by hemodialysis and urea is one of these substances (col. 4, lines 50-54). Buck teaches urea clearance versus bloodflow at different ultrafiltration rates presented in Fig. 8. It would have been obvious to one of ordinary skill in the art to optimize the claimed pore size and density of a surface layer

Art Unit: 1782

to increase the diffusive permeability motivated by Gorsuch and Wang which teach that the flux is controlled by the pore size, density and virtual membrane thickness.

As to claim 5, Buck teaches a hydrophobic polymer between about 85-95% and a hydrophilic polymer between about 5-15% (col. 2, lines 26-32).

As to claim 6, Buck teaches the hydrophobic polymers are polyamides, polyarylsulphone, polycarbonate as disclosed in col. 2, lines 33-45).

As to claim 7, Buck teaches hydrophilic polymers such as polyvinylpyrrolidone, polythyleneglycol, polypropyleneglycol, water soluble cellulosic derivative as disclosed in col. 2, lines 40-45).

As to claim 20 and 21, Buck teaches a hollow fiber membrane for use in hemodiafiltration and dialysis and filtration.

As to claims 24 and 25, Buck differs and does not teach the pore density on the outer surface layer is between 18,000 to 100,000 or between 20,000 to 100,000. Wang teaches the density of the skin pores is at least 8 pores per 1000 micron² and more than 50 pores per 1000 micron² (col. 13, lines 13-34). This is equivalent to 8,000 to 50,000 pores per mm² and in the claimed range. Wang teaches the higher the membrane porosity, the faster the plasma transfer rate. A low degree of surface porosity, even with a high degree of asymmetry appears to cause blocking or clogging and a slower separation (col. 14, lines 47-55). Wang teaches the asymmetry is due to the difference in pore size from the surface which is 0.1 micron which gradually increases to a course pore surface having pore sizes up to 100 micron (col. 5, lines 20-25). Wang presents a finding that one of ordinary skill in the art could have combined

Art Unit: 1782

the features of pore size and density of Wang's surface layer in the four layer hollow fiber structure of Buck and Gorsuch and the results of the combination would have been predictable in producing a hollow fiber membrane with improved the flow rate and separation rate.

2. Claim 4 rejected under 35 U.S.C. 103(a) as unpatentable over Buck (US 4,935,141) in view of Wang et al (US 6,045,899) and Gorsuch et al (US 6,802,971) and in further view of Aptel et al (US 4,882,223).

As to claim 4, Buck teaches an inner layer thickness of 1 to 20 micron, a second layer thickness of 3 to 5 micron and a third layer thickness of 20 to 60 micron. As noted above, Buck does not explicitly teach a fourth layer and Gorsuch is relied upon for teaching a four layer structure. Gorsuch differs and does not teach the zone thicknesses.

Aptel teaches non-symmetrical hollow fibers presenting a relatively dense layer ('skin') (H) of a very small thickness at their outer periphery which is bound to an open structure of which the porosity increases in the direction to the inner face; their porous structure comprises microvoids shaped like elongate fingers. Aptel is teaching a thin outer porous surface layer can be produced over the elongate finger layer of a hollow fiber membrane. Fig. 3 of Aptel shows a schematic of the outer surface layer E that can be employed on the elongate finger layer. Fig. 8 is a photomicrograph of the hollow fiber membrane.

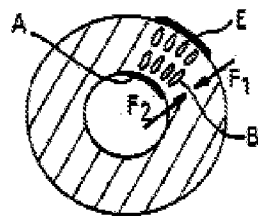
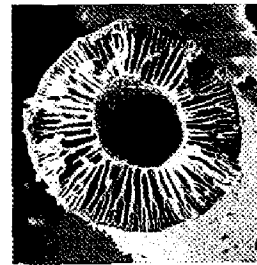


FIG. 3



50 μm

FIG. 8

Aptel teaches the outer surface layer has a pore size of 0.1 to 2 micron and in the claimed range. Aptel teaches the thickness of the outer skin layer is lower than 1 micron (col. 2, lines 9-30). Applicant is claiming a thickness of the outer surface layer of 1 to 10 micron. Aptel teaches a layer that is approximately 1 micron which overlaps the claimed range. Gorsuch teaches the flux is dependent on the pore size, porosity and virtual membrane thickness (col. 3, lines 13-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the fourth and outer layer thickness motivated to control and increase the membrane flux.

Response to Arguments

3. Applicant's arguments and Rule 1.132 Declaration, with respect to Kawata have been fully considered and are persuasive. The 35 USC 103 rejection of claims 1, 3, 5-7, 20-21 and 24-25 has been withdrawn. Applicant's arguments with respect to claim 1, 3-7, 20-21 and 24-25 have been considered but are moot in view of the new ground(s) of rejection. New 35 USC 103 rejection of claims 1, 3, 5-7, 20-21 and 24-25 over Buck

Art Unit: 1782

in view of Gorsuch and Wang is presented in this Office Action and as well as 35 USC 103 rejection of claim 4 over Buck in view of Gorsuch, Wang and Aptel.

4. Applicant submitted a Rule 1.132 Declaration explaining how to calculate the pore density from Fig. 1 of Kawata. Applicant's declaration is sufficient to show that Kawata does not teach the claimed surface pore density.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER STEELE whose telephone number is (571)272-7115. The examiner can normally be reached on Office Hours Mon-Fri 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1782

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. S./
Examiner, Art Unit 1782

7/13/2010

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1782